IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA SOUTHERN DIVISION

No. 7:23-cv-00897

)	DEFENDANT UNITED STATES
)	OF AMERICA'S MEMORANDUM OF
)	LAW IN SUPPORT OF MOTION TO
)	EXCLUDE UNTIMELY GENERAL
)	CAUSATION OPINIONS
)	(Fed. R. Civ. P. 16, 37; L. Civ. R. 7)
)))))

The United States submits the following Memorandum of Law in support of its Motion to Exclude Untimely Plaintiffs' Leadership Group ("PLG") General Causation Opinions.

INTRODUCTION

This Court methodically structured expert discovery in this litigation into three phases: water contamination issues at Camp Lejeune (Phase I); general causation for the five Track 1 diseases (Phase II); and residual issues, including specific causation for the Track 1 Trial Plaintiffs and damages (Phase III). (See 270, 312, 3321; collectively, the "Court's Scheduling Orders.") This sequencing prioritized the resolution of key threshold issues—such as general causation—and was thereby designed to resolve the Track 1 cases efficiently and to facilitate global resolution efforts. The Court required disclosure of PLG's experts on general causation by December 9, 2024. Months after that deadline, however, PLG disclosed numerous general causation opinions across its Phase III reports. As these Phase III experts are being deposed (the first of which occurred on May 30, 2025, and they are ongoing), it has become clear that they are offering general causation opinions of their own, independent of PLG's Phase II experts.

¹ D.E. <u>332</u> established extended deadlines for the United States' Phase III expert disclosures for the Parkinson's Disease Plaintiffs.

PLG cannot show good cause for these untimely disclosures. Crucially, because these opinions were untimely disclosed in Phase III, the United States was deprived of any opportunity to respond through its Phase II general causation experts—as the Court's phased structure intended. PLG's untimely general causation opinions should be excluded.

BACKGROUND

On August 7, 2024, this Court entered a pretrial schedule to govern expert discovery. (D.E. 270) PLG's Phase II disclosures were due on December 9, 2024. (See id. ¶ 5.) On January 2, 2025, this Court set PLG's Phase III disclosure deadline as February 7, 2025. (See D.E. 312 at 3.) The United States' Phase II disclosures were also due on the same date. (*Id.*)

On February 7, 2025, PLG disclosed a large number of specific causation reports among the Phase III reports (excluding other experts, like life care planning or economics), as follows:

Track 1 Disease	Number of Specific Causation Reports
Bladder Cancer	15
Kidney Cancer	17
Leukemia	5
Non-Hodgkin's Lymphoma	5
Parkinson's Disease	5

PLG disclosed 47 specific causation Phase III reports from a myriad of experts. Depositions of these experts are scheduled throughout June and July of 2025. Although PLG's Phase II opinions on general causation were due on December 9, 2024, many of PLG's Phase III reports disclosed on February 7, 2025, improperly contained general causation opinions in violation of the Court's Scheduling Orders. These are set out below by Track 1 disease.

Bladder Cancer. Thomas Longo, M.D., disclosed Phase III reports in Criswell v. United States (7:23-cv-01482) and Dyer v. United States (7:23-cv-00357), both of which included sections entitled, "General Causation." (See Ex. 1, Longo Criswell Rep., at 11-14; Ex. 2, Longo Dyer Rep.,

at 13-16.)² Similarly, *John Sfakianos*, *M.D.*, included "General Causation" sections in his Phase III reports in Cagiano v. United States (7:23-cv-00569) and Laramore v. United States (7:23-cv-00594). (See Ex. 3, Sfakianos Cagiano Rep., at 11-12; Ex. 4, Sfakianos Laramore Rep., at 9-11.) Inexplicably, Dr. Sfakianos and Dr. Longo include verbatim descriptions of the purpose of their general causation sections: to address "whether there is enough evidence to establish whether the chemicals in the water at Camp Lejeune are capable of causing bladder cancer as a general matter." (Exs. 1, 2, 3, and 4.) At his deposition on June 16, 2025, Dr. Longo admitted that he performed "[his] own literature review" and "drew [his] own independent conclusions" as to the epidemiological studies before allegedly deferring "to the epidemiologists[.]" (Ex. 5, Longo Dep., 117:19-118:1.) Dr. Longo also admitted that his "General Causation" section was identical to that of Dr. Sfakianos' Phase III reports, which he claimed he had not seen before. (Id. at 170:16-173:14.) Finally, Vincent Bivins, M.D., opines in his Phase III report in Raymond v. United States (7:23-cv-00546) that TCE and benzene are "hazardous to human health generally[.]" (Ex. 6, Bivins Raymond Rep., at 11-15 (emphasis added).)

Kidney Cancer. Vitaly Margulis, M.D., disclosed a Phase III report in Downs v. United States (7:23-cv-01145) containing detailed general causation opinions, including at least one new study. (See Ex. 7, Margulis Downs Rep., at 7-14.) Yair Lotan, M.D., submitted Phase III reports in Downs and in Fancher v. United States (7:23-cv-00275) that similarly contained general causation opinions. (See Ex. 8, Lotan Downs Rep., at 2, 3-4, 7-11, 16-22; Ex. 9: Lotan Fancher Rep., at 2, 3-4, 6-11, 14-18, 18-20.) Dr. Lotan also purported to analyze the Bradford-Hill factors,

² To avoid unnecessary filings, the United States is filing the relevant excerpts of each Report at issue in this Motion. The United States will file the full report upon the Court's request.

which solely relate to general causation.³ *Joseph J. Del Pizzo, M.D.*, similarly attempts to analyze the Bradford-Hill factors in *Howard*, *Fancher*, and *Mousser v. United States* (7:23-cv-00667). (*See* Ex. 10, Del Pizzo *Howard* Rep., at 5-10, 16-18; Ex. 11, Del Pizzo *Fancher* Rep., at 5-10, 15-17; Ex. 12, Del Pizzo *Mousser* Rep., at 6-12, 18-20.) Finally, *Armine K. Smith, M.D.*, disclosed Phase III reports in *Howard*, *Mousser*, and *Tukes v. United States* (7:23-cv-01553), in which she offers general causation opinions based on an independent review of toxicologic, mechanistic, and epidemiologic evidence relating to kidney cancer. (*See* Ex. 13, Smith *Howard* Rep., at 6-10; Ex. 14, Smith *Mousser* Rep., at 7-12; and Ex. 15, Smith *Tukes* Rep., at 8-12.)

Leukemia. Damian Laber, M.D., disclosed Phase III reports in Fiolek v. United States (7:23-cv-00062) and Gleesing v. United States (7:23-cv-01486). In both reports, Dr. Laber opined that "there is a causal relationship between TCE, PCE, and benzene exposure at Camp Lejeune and [chronic lymphocytic leukemia]," a general causation opinion that was specific to the leukemia subtype CLL. (See Ex. 16, Laber Fiolek Rep., at 11; Ex. 17, Laber Gleesing Rep., at 11.) Dr. Laber therefore went beyond the scope of PLG's timely general causation opinions, which addressed "leukemia" generally.

Non-Hodgkin's Lymphoma. Richard T. Hoppe, M.D., disclosed Phase III reports in Davis v. United States (7:23-cv-00043) and Howard v. United States (7:23-cv-00490). Dr. Hoppe included an extensive analysis of epidemiological studies on TCE, PCE, and benzene, as well as ATSDR's Assessment of the Evidence (2017). (See Ex. 18, Hoppe Davis Rep., at 2-6; Ex. 19, Hoppe Howard Rep., at 2-6.) The United States deposed Dr. Hoppe on June 9, 2025. Dr. Hoppe agreed that he offered a general causation analysis in Davis and Howard. (See Ex. 20, at 32:11-

³ See Federal Judicial Center, Reference Manual on Sci. Evid. at 599-600 (3d ed. 2011) ("The factors that guide epidemiologists in making judgments about causation are [the Bradford Hill factors].")

15.) Dr. Hoppe admitted that he was not aware of the Court's phased approach to expert discovery. (Id. at 34:18-22.) He further admitted that "a lot of [his general causation analysis] was [his] own" based on his "own review of the materials." (Id. at 36:8-11.) Dr. Hoppe performed "some searches," but also reviewed "citations provided . . . by the attorneys." (Id. at 37:22-38:2.) Paul J. Michaels, M.D., disclosed a Phase III report in Vidana v. United States (7:23-cv-01575). Dr. Michaels opined that, as a general matter, TCE, PCE, and benzene are carcinogenic and increase the risk of NHL in animals and humans. (See Ex. 21, Michaels Vidana Rep., at 1, 6-13.) He then analyzed numerous epidemiological studies at length. (*Id.* at 6-13.)

Parkinson's Disease. Richard L. Barbano, M.D., disclosed Phase III reports in Peterson v. United States (7:23-cv-01576) and McElhiney v. United States (7:23-cv-01368). In both reports, Dr. Barbano opines that "[t]here is ample evidence that neurotoxins are sufficient to cause neurodegenerative diseases such as Parkinson's disease," along with other general causation opinions, including that "these toxins are at least as likely as not to cause Parkinson's disease." (See Ex. 22, Barbano Peterson Rep., at 14; Ex. 23, Barbano McElhiney Rep., at 14.) Dr. Barbano also purports to analyze the Bradford-Hill factors, which solely relate to general causation. (See Ex. 22, at 17-18; Ex. 23, at 17-18.) *Heidi B. Schwarz, M.D.*, disclosed Phase III reports in *Sparks* v. United States (7:23-cv-00682) and Welch v. United States (7:23-cv-01503). She extensively analyzes the "body of literature" on whether TCE "is a risk for developing Parkinson's disease." (See Ex. 24, Schwarz Sparks Rep., at 5-6; Ex. 25, Schwarz Welch Rep., at 6-7.) Dr. Schwarz also considers the Bradford-Hill factors. (See Ex. 24, at 12; Ex. 25, at 14-15.) Finally, Kristin Andruska, M.D., disclosed a Phase III report in Rothchild v. United States (7:23-cv-00858), in which she opined independently about general causation at length. (See Ex. 26, Andruska Rothchild Rep., at 44-56, 61-62, 64 ("I have also conducted my own review and concluded that it is as at least as likely as not that exposure to the water at Camp Lejeune, contaminated with PCE and TCE, can cause Parkinson Disease.").)

LEGAL STANDARD

The Pretrial Scheduling Order (D.E. 270) and Amended Pretrial Scheduling Order (D.E. 312) established a clear deadline for Phase II disclosures. "Accordingly, the [C]ourt's inquiry into whether there have been any violations is governed by Rule 16(f)." *In re Camp Lejeune Water Litig.*, No. 7:23-CV-897, 2025 WL 1343184, at *3 (E.D.N.C. May 8, 2025) (citations omitted). "Next, the [C]ourt must determine what sanction, if any, is appropriate." *Id.* at 5. "The main consideration of a Rule 16(f) analysis is 'whether [PLG] has shown good cause for its failure to timely disclose." *Id.* (citations omitted). As this Court has recently noted, "[w]hen making this analysis, courts in this district have often applied the factors set out in out in *Akeva [LLC v. Mizuno Corp.*, 212 F.R.D. 306, (M.D.N.C. 2002)]." *Id.* Those factors include:

[S]pecifically: (1) the explanation for the failure to obey the order; (2) the importance of the expert opinion; (3) the prejudice to the opposing party by allowing the disclosures; (4) the availability of alternative or lesser sanctions; (5) the interest in expeditious resolution of litigation; (6) a court's need to manage its docket; and (7) public policy favoring disposition of cases on the merits.

In re Camp Lejeune Water Litig., 2025 WL 1343184, at *5 (citing Severn Peanut Co. v. Indus. Fumigant Co., No. 2:11-CV-00014-BO, 2014 WL 198217, at *3 (E.D.N.C. Jan 15, 2014)).

ARGUMENT

PLG's untimely disclosure of Phase II opinions in Phase III violates the Court's Scheduling Orders. Because PLG cannot show good cause for these late disclosures—and the United States has faced significant prejudice as a result—exclusion under Rule 16(f) is warranted and necessary to preserve the integrity of the Court's structured discovery process.

I. PLG's Phase III Reports Disregard the Court's Scheduling Orders.

By disclosing Phase II general causation opinions nearly two months late—on February 7, 2025—PLG violated the Court's Scheduling Orders. (*See* D.E. <u>270</u>; D.E. <u>312</u>.) These opinions were served on the very day the United States was required to submit its own Phase II reports, disregarding the deliberate structure and sequencing the Court established for phased expert discovery.

Further, PLG's Phase III experts have made clear that they are offering their own general causation opinions, independent of the previously-disclosed Phase II opinions. In some instances, PLG's Phase III experts have conducted their own literature reviews related to general causation or even their own Bradford-Hill analyses. For example, on June 9, 2025, one of PLG's NHL experts, Dr. Hoppe, candidly admitted that "a lot of [his general causation analysis] was [his] own" based on his "own review of the materials." (Ex. 20 at 36:8-11.) Likewise, although Dr. Longo claimed that he deferred to PLG's epidemiologists, he emphasized that he performed his own "literature search" and analysis in his Phase III report on bladder cancer. (Ex. 5 at 117:19-118:1.)

Thus, PLG's disclosure of untimely general causation opinions violates the Court's Scheduling Orders. The question is now whether sanctions are warranted under Rule 16(f). Here, all of the *Akeva* factors weigh in favor of exclusion.

II. PLG's Lack of Good Cause and the Akeva Factors Warrant Exclusion.

The *Akeva* framework guides the Court in evaluating Rule 16(f) violations, and each factor, addressed in turn, supports exclusion here.

First, the Court should consider "the explanation for the failure to obey the [Court's Scheduling Orders.]" *Akeva*, 212 F.R.D. at 311. PLG cannot offer a legitimate explanation for its noncompliance. The Court's Scheduling Orders were clear, and PLG was directly involved in negotiating the proposed expert disclosure schedule and submitting it to the Court. Courts have

excluded other late disclosures in phased expert discovery. *See In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, MDL No. 15-2666, 2018 WL 5801901, at *2-3 (D. Minn. Nov. 6, 2018) (affirming exclusion of untimely general causation opinions); *see also In re Bendectin Litig.*, 857 F.2d 290, 317-20 (6th Cir. 1988) (affirming exclusion of evidence irrelevant to sole issue of proximate causation, reasoning that "trifurcating this case on the separate issue of proximate causation was proper" because it "promoted efficiency, and did not unduly prejudice plaintiffs").

In *Bair Hugger*, the court rejected the plaintiffs' attempt to offer general causation opinions during the case-specific phase—despite the plaintiffs' explanation that the disclosure was substantially justified and harmless. 2018 WL 5801901, at *2. The court also noted that the plaintiffs had already been given the opportunity to present such opinions during the earlier general causation phase, and allowing them to supplement or introduce new expert reports later "would undermine the efficiency of the MDL and the purpose behind bifurcating discovery." *Id.* That same reasoning rings true here. Thus, the first factor under *Akeva* weighs heavily in favor of exclusion.

Second, the Court should assess "the importance of the expert opinion[.]" Akeva, 212 F.R.D. at 311. PLG has already disclosed its Phase II experts on general causation—15 of them. Given that PLG already disclosed general causation opinions in Phase II, the untimely opinions served in Phase III carry no meaningful importance under this factor.

During the June 16, 2025, meet and confer, PLG argued that their Phase III experts needed to "rule in" the Camp Lejeune water as a possible cause before conducting a differential diagnosis. But this argument rings hollow. PLG designated Phase II experts to address that task. And other PLG Phase III experts complied with the Court's framework while "ruling in" exposure at Camp Lejeune as a possible factor in a differential diagnosis. For example, Dr. Matthew Cooper in

Mousser reviewed Plaintiffs' Phase II general causation opinions concerning kidney cancer, adopted them, and relied on them to conduct his specific causation analysis without offering any untimely general causation opinions. (*See* Ex. 27, Cooper *Mousser* Rep., at 10-13.)

Third, the Court should consider "the prejudice to the [United States] by allowing the disclosures [.]" Akeva, 212 F.R.D. at 311. PLG's late disclosures deprived the United States' Phase II experts of any opportunity to respond. PLG's untimely Phase II general causation opinions were disclosed on the same day the United States was required to serve its own Phase II expert reports addressing general causation, making any meaningful response impossible. And the prejudice is not alleviated by any assertion from counsel (i.e., PLG) that the opinions are not "new" simply because they rely on previously disclosed literature or similar methodologies. That argument misses the point. If the opinions are not new, the prejudice remains because, if PLG is unsuccessful on general causation for a particular disease in Phase II, it would nevertheless retain general causation opinions preserved in Phase III reports—opinions that exist solely because they were disclosed in violation of the Court's Scheduling Orders. And if the opinions do differ in any material respect, whether in their conclusions, methodologies, or the literature on which they rely, the prejudice is even more apparent. In short, the prejudice here is that the United States was deprived of any opportunity to evaluate, probe, or rebut the opinions at issue through its own Phase II experts.

Fourth, the Court should assess "the availability of alternative or lesser sanctions." *Id.* (citations omitted). No lesser sanction can unwind the damage of PLG's untimely disclosures—at least not without risking significant disruption to the Court's schedule. *See SMD Software, Inc. v. EMove, Inc.*, No. 5:08-CV-403-FL, 2013 WL 5592808, at *9 (E.D.N.C Oct. 10, 2013) (Flanagan, J.) (permitting lesser sanctions where they alleviated prejudice and preserved the trial schedule).

Because of the Court's methodical structure of expert discovery and the Parties' careful planning and preparation in reliance on it, the United States asserts that the only non-prejudicial remedy is to exclude PLG's untimely Phase II opinions disclosed in Phase III. No lesser sanction can alleviate the harm and preserve the orderly progression of this litigation.

Finally, the remaining Akeva factors for the Court to consider include "the interest in expeditious resolution of litigation; [the] [C]ourt's need to manage its docket; and public policy favoring disposition of cases on the merits." Akeva, 212 F.R.D. at 311 (citation omitted). Allowing PLG's untimely disclosures risks delaying Phase III and undermining the Court's carefully sequenced discovery schedule, which was designed for the efficient resolution of cases. It also renders the Phase II briefing schedule meaningless; even if the United States were to succeed in excluding PLG's Phase II opinions, PLG may simply attempt to rely on its new general causation opinions in Phase III. "The factors involving docket control planning are sufficiently important to alone justify the exclusion of an untimely disclosed expert report or opinion even in absence of prejudice to the opposing party." Id. (citation omitted). Exclusion of these late opinions will therefore promote resolution on the merits by preserving the Court's phased discovery structure, which ensures that Phase II remains focused on general causation and Phase III on specific causation.

CONCLUSION

In sum, all seven *Akeva* factors weigh in favor of exclusion. PLG cannot show good cause for disregarding the Court's Scheduling Orders, which the parties jointly proposed. The untimely general causation opinions add little to no value in Phase III and have significantly prejudiced the United States, which had no fair opportunity to respond through its Phase II experts.

Accordingly, the United States asks that the Court grant this Motion and exclude all of PLG's untimely general causation opinions.

Dated: June 23, 2025 Respectfully submitted,

BRETT A. SHUMATE Assistant Attorney General, Civil Division

JONATHAN GUYNN Deputy Assistant Attorney General, Torts Branch

J. PATRICK GLYNN
Director,
Environmental Torts Litigation Section

BRIDGET BAILEY LIPSCOMB Chief, Camp Lejeune Unit

ADAM BAIN Special Litigation Counsel

JOSHUA G. CARPENITO DAVID R. ORTIZ Trial Attorneys

/s/ Joshua G. Carpenito
Joshua G. Carpenito
NC Bar No. 60801
Trial Attorney
United States Department of Justice
Civil Division, Torts Branch
Environmental Torts Litigation
310 New Bern Ave,
Raleigh, NC 27601
202-880-1518
joshua.g.carpenito@usdoj.gov

Attorney inquiries to DOJ regarding CLJA: (202) 353-4426

Attorneys for Defendant, United States of America

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2025, I electronically filed the foregoing using the Court's Electronic Case Filing system, which will send notice to all counsel of record.

> /s/ Joshua G. Carpenito Joshua G. Carpenito